

Biosafety Guidelines: Policies & Procedures



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Institutional Biosafety Committee (IBC)

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1 Introduction

Universities, hospitals, and other institutions that conduct federally funded research utilizing recombinant or synthetic nucleic acids and techniques are required by federal law to establish a committee responsible for reviewing such proposed research. Federal rules governing this research are primarily described in the *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* ([NIH Guidelines](#)). In order to maintain funding or to stay eligible for funding the university must comply with these regulations.

To comply, North Dakota State University has established an Institutional Biosafety Committee, the “IBC.” This manual, *NDSU Biosafety Guidelines: Policies and Procedures*, has been created by the NDSU IBC and is based on guidelines established by federal regulations, best practices and the *Biosafety in Microbiological and Biomedical Laboratories 6th Edition* ([BMBL](#)) as well as additional policies for research conducted within the NDSU system.

The NDSU Biosafety Guidelines are designed to minimize or eliminate potential adverse effects on human, plant, and animal health, and the environment, from research, clinical, and educational activities involving the following potential biohazards:

- Recombinant or synthetic nucleic acids
- Infectious Agents
- Human Blood, Bodily Fluids and Tissues

As part of a cooperative agreement with the Agricultural Research Service, United States Department of Agriculture (USDA), the NDSU IBC will act and function as the IBC of record for the facilities located on the NDSU campus that are both USDA owned and operated. A Memorandum of Understanding (MOU) has been established that gives the NDSU IBC full authority and oversight for all rDNA work performed by the USDA locally. The MOU is renewed every 5 years.

1.1 Scope

These *NDSU Biosafety Guidelines* apply to employees and students that conduct clinical, research, and/or teaching activities as described in Section 2.1. Outside organizations using NDSU facilities and/or equipment also must follow the *NDSU*

Biosafety Guidelines, and submit protocol applications listing an NDSU contact person as responsible party.

1.2 Regulatory Authority

The *NDSU Biosafety Guidelines* are based on several regulatory requirements, as well as nationally recognized consensus standards and guidelines. The following list is not inclusive of all regulations and/or requirements that may pertain to any given project. Other requirements may apply depending on other factors, such as, but not limited to, concurrent use of radioactive materials, live animals, and human subjects, or additional specific funding organization requirements. Principal Investigators (PIs) must familiarize themselves with all requirements pertaining to their particular projects.

The federal regulations and guidelines that follow are the basis for the NDSU biosafety program. This list is not all-inclusive. In cases where federal, state, and local regulations differ, NDSU will follow the most stringent regulations.

- **Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules** (herein referred to as “NIH Guidelines”), U.S. Department of Health and Human Services, National Institutes of Health. 59 FR 34496 (Final Rule) and subsequent amendments. <http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines>
- **Biosafety in Microbiological and Biomedical Laboratories, 6th Ed.** (herein referred to as “BMBL” or “CDC Guidelines”), U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention. <https://www.cdc.gov/labs/BMBL.html>
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- **49 CFR Parts 171-177, Hazardous Materials Regulations.** U.S. Department of Transportation. <http://energy.gov/nepa/downloads/49-cfr-parts-171-177-hazardous-materials-regulations-dot>
- **42 CFR Part 73, Select Agents and Toxins.** <http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=8a4be60456973b5ec6bef5dfeaffd49a&r=PART&n=42y1.0.1.6.61>

- **Dangerous Goods Regulations (DGR).** International Air Transport Association (IATA). <http://www.iata.org/publications/dgr/Pages/index.aspx>
- **29 CFR 1910.1030, Blood-borne Pathogens.** U.S. Department of Labor, Occupational Safety and Health Administration. https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051
- **42 CFR Parts 71 and 72, Control of Communicable Diseases.** U.S. Dept. of Health and Human Services, Center for Disease Control and Prevention. <http://www.cdc.gov/quarantine/final-rules-control-communicable-diseases.html>
- **9 CFR Parts 92, 94, 95, 96, 122, and 130. Importation of Etiologic Agents of Livestock, Poultry, and Other Animal Diseases.** US Dept. of Agriculture, Animal and Plant Health Inspection Service. <http://www.aphis.usda.gov/wps/portal/aphis/home/>
- **7 CFR Part 330. Importation and Domestic Transfer of Plant Pests.** US Dept. of Agriculture, Animal and Plant Health Inspection Service. <http://www.aphis.usda.gov/wps/portal/aphis/home/>
- **15 CFR Parts 730 to 799. Export of Etiologic Agents of Humans, Animals, Plants, and Related Materials.** U.S. Dept. of Commerce, Bureau of Industry and Security. <http://www.bis.doc.gov/index.php/regulations/export-administration-regulations-ear>
- **49 CFR Parts 100 to 185. Hazardous Materials Regulations.** U.S. Dept. of Transportation. <http://www.phmsa.dot.gov/hazmat/standards-rulemaking/hmic>

1.3 Resources and Contact Information

Resources available to assist with compliance with NDSU Biosafety Guidelines include the following agencies and documents.

- NDSU Police and Safety Office (UP&SO) SOPs for Biological Waste Handling and Disposal, Sharps Containment and Disposal, Blood-borne Pathogen

Program, Emergency Response to Biological Spills, [Respirator Fit program](#). SOPs can be accessed through the Safety Office website at http://www.ndsu.edu/police_safety/ or by calling 1-7759.

- USDA-ARS SOPs are available through the ARS internal server on the P:\Safety, including the Chemical Hygiene Plan, Biological Safety Plan, and Crisis Management Plan.
- Centers for Disease Control and Prevention, Biosafety Branch, Atlanta, Georgia 30333, Phone 1-800-232-4636, www.cdc.gov/biosafety
- National Institutes of Health, Division of Occupational Health and Safety, <http://www.ors.od.nih.gov/sr/dohs/Pages/default.aspx#>
- National Animal Disease Center, U.S. Department of Agriculture, http://ars.usda.gov/main/site_main.htm?modecode=36-25-30-00
- Animal and Plant Health Inspection Service, U.S. Department of Agriculture, <http://www.aphis.usda.gov/wps/portal/aphis/home/>
- Collaborative Institutional Training Initiative www.citiprogram.org

1.4 Violations

Violations of regulatory requirements regardless of the specific funding source can jeopardize funding from the National Institutes of Health (NIH), United States Food and Drug Administration (FDA), United States Department of Agriculture (USDA), United States Environmental Protection Agency (EPA), National Science Foundation (NSF), and other granting agencies for all of NDSU. Non-conformance with regulatory requirements and nationally recognized standards may also endanger human or animal health and/or the environment.

[NDSU Policy 347: Institutional Biosafety Committee](#) applies to projects conducted at NDSU facilities, or conducted by representatives of NDSU. Project investigators are responsible for submitting the protocol forms required for review and approval by the NDSU IBC.

Violations of NDSU Policy 347 are subject to procedures outlined in Biosafety Guidelines *Section 4 Noncompliance and Corrective Actions*, and may result in

disciplinary action up to and including termination. Examples may include failure to provide required annual updates to the IBC or complete training requirements.

2 Guideline Elements

Two components of the *NDSU Biosafety Guidelines* are the identification of requirements applicable to general categories of biohazard work (Section 2.1) and the protocol development process including approvals that must be obtained for projects (Section 2.2). The other components include packaging and shipping dangerous goods, waste handling, training, and facility issues (Sections 2.3 through 2.6).

2.1 Specific Requirements for Projects

Five general categories of work are addressed in these guidelines:

- Recombinant or synthetic nucleic acid projects (Section 2.1.1)
- Infectious Agent projects (Section 2.1.2)
- Human Blood, Bodily Fluids or Tissue projects (Section 2.1.3)
- Select Agents/Biological Toxins (Section 2.1.4)
- Dual Use Research of Concern (DURC) (Section 2.1.5)

The Institutional Biosafety Committee (IBC) protocol approval process referred to throughout Section 2.1 is more fully described in Section 2.2.

2.1.1 Recombinant or Synthetic Nucleic Acid Projects

All projects involving recombinant or synthetic nucleic acids must be reviewed by the IBC. The purpose of IBC review of exempt protocols is to verify the project is applicable to one or more of the “exempt” categories outlined in the *NIH Guidelines*. The purpose of the IBC review of non-exempt protocols is two-fold: 1) to ensure safety and compliance, 2) to verify whether the project is subject to notification to and/or approval by NIH or other regulatory agency (e.g., FDA, APHIS, etc.). The approval process

requires the PI to complete the [Institutional Biosafety Application](#), available on the IBC web site.

2.1.2 Infectious Agents Projects

The level of review for clinical, research, or teaching projects involving agents infectious to humans, plants, or animals depends on the Risk Group (RG) classification of the respective agent.

A. Risk Group 1 Organisms

RG 1 agents are not associated with disease in healthy adult humans. Work can be conducted on an open bench top using standard microbiological practices as described in the [BMBL](#). Clinical, research, and teaching projects using RG 1 agents must follow the IBC approval procedures described in Section 2.2. The approval process requires the PI to complete the [Institutional Biosafety Application](#).

B. Risk Group 2 Organisms

RG 2 agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are *often* available. Clinical, research, and teaching projects using RG2 agents must follow the IBC approval procedures described in Section 2.2. The approval process requires the PI to complete the Institutional Biosafety Application, and have a current culture list, biosafety manual and current lab inspection on file with the Safety Office.

B. Risk Group 3 Organisms

RG 3 agents are associated with serious or lethal human disease for which preventative or therapeutic interventions *may* be available. Research projects using RG3 agents must follow the IBC approval procedures described in Section 2.2. The approval process requires the PI to complete the Institutional Biosafety Application, have a current culture list, biosafety manual and current lab inspection on file with the Safety Office.

D. Risk Group 4 Organisms

RG 4 agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are *not usually* available.

Work involving RG 4 agents **would not** be allowed because adequate containment facilities are not available at NDSU at this time.

E. Considerations

Careful consideration should be given to the types of manipulation planned for some higher Risk Group agents. When such agents are used for animal inoculation or transmission studies, a higher containment level is recommended. (See the *NIH Guidelines*, [Section II-A-3](#), *Comprehensive Risk Assessment*)

2.1.3 Human Blood, Bodily Fluid or Tissue Projects

Research and teaching laboratory projects involving the culture, production, concentration, experimentation, and manipulation of human blood, bodily fluids or tissues (including cell lines) are subject to review and approval by the IBC. The approval process requires the PI to complete the Institutional Biosafety Application and have a current lab inspection on file with the Safety Office. This work will be performed at a BSL-2 level.

The NDSU *Blood borne Pathogen/Exposure Control Plan* applies to projects of this nature. The Exposure Control Plan is located on the UP&SO website:
http://www.ndsu.edu/police_safety/

Employees and students who have exposure to blood borne pathogens will be offered the Hepatitis B vaccine series at no cost to themselves. Contact the [UP&SO](#) at 701-231-7759 for information on the Hepatitis B series.

2.1.4 Select Agents / Biological Toxins

Research and teaching laboratory projects involving select agents/biological toxins do not fall under NDSU IBC purview. Investigators who plan to use select agents/biological toxins are advised to contact the NDSU Responsible Official (RO) through the IBC Office (701-231-8908).

Select agent information also may be found at www.selectagents.gov .

Additional information on requirements when working with toxins is available from the NDSU Laboratory and Chemical Safety Committee by contacting the [UP&SO](#) at 701-231-7759.

2.1.5 Dual Use Research of Concern (DURC)

Research that would fall under this category will be evaluated by the Institutional Review Entity (IRE), an *ad hoc* subcommittee of the IBC. The IRE will determine what requirements must be completed.

2.2 Protocol Development, Approval, and/or Oversight

When IBC approval is required, as described in Section 2.1, the steps described in Section 2.2 must be followed.

2.2.1 Project Proposal Development

The IBC approval process begins with the Principal Investigator (PI), or responsible authority conducting clinical, research, and teaching activities listed in Section 2.1, completing the [Institutional Biosafety Application](#). Additionally, a laboratory-specific biosafety plan must be developed by the PI where existing plans do not address all the safety aspects of the project.

The PI must develop and implement a lab-specific biosafety manual for all BSL-2 work identified by the IBC office commensurate with the risk of the agent(s) and intended use. The plan must contain sufficient information to describe biosafety and containment procedures, and should be reviewed annually. ([BMBL 6th ed.](#))

2.2.2 Exempt Recombinant or Synthetic Nucleic Acids, Infectious Agent or Human Blood, Bodily Fluid or Tissue Protocol Review

After completing the application form, the PI must obtain the signature of the department head/chair or Unit Research Leader (USDA). Following signature by the department head/chair, the PI forwards the protocol to the IBC Office. The IBC Office will review the protocol to ensure it is complete and take necessary steps to preserve the confidentiality of any project involving proprietary matters.

Exempt Biosafety Level 1 projects may be initiated upon submission of the protocol, provided all applicable training has been completed in accordance with the NIH Guidelines.

Note Projects requiring Biosafety Level 2 or higher may not proceed until all required approvals are in place.

Designated Member Review (DMR)

- Each exempt protocol is distributed to the entire IBC with specific instructions regarding the designated member review process and a deadline to call for FCR which is 5 business days. Affirmation from all IBC members is not required.
- Under extenuating circumstances, the deadline can be reduced by the IBC Chair/designee to a minimum of one day with affirmation required from all members regarding their decision whether or not to call for FCR.
- **Designate Member Review Assignment**
Two members of the IBC are assigned by the chair in rotation.
- Any member of the IBC can make the decision to send the protocol for FCR at any time during the set deadline period. If no member of the IBC refers the protocol to full committee review at a convened meeting, at the end of the set deadline period the assigned IBC DRs have the authority to approve, require modifications in (to secure approval) or request full committee review.
- The DR decisions must be unanimous; if not, the protocol will be referred for FCR. The DRs do not have the power to withhold approval.
- The IBC minutes contain notification of all actions approved by DMR.

Administrative Review

- The Request for Change form will be reviewed by IBC Office personnel.
- The IBC Chair will make a determination or refer the change request to DMR or FCR.

2.2.3 Non-exempt Recombinant or Synthetic Nucleic Acids Protocol Review

After completing the Application form, the PI must obtain the signature of the department head/chair or Unit Research Leader (USDA). Following signature by the department head/chair, the PI forwards the protocol to the IBC Office. If the application is received by the 15th, it will be reviewed at the next month's meeting. The IBC Office will review the protocol to ensure it is complete and take necessary steps to preserve the confidentiality of any project involving proprietary matters.

Projects may not proceed until all required approvals are in place.

Full Committee Review (FCR)

- Full committee review of protocols requires a convened meeting of a quorum of the IBC members. For a protocol to be approved, it must receive the approval of the majority of those members present at the convened meeting.
- Protocols scheduled for full IBC review are distributed to all members of the IBC at least one week prior to the meeting. The IBC meets once per month with additional meetings to address extenuating circumstances convened when necessary.
- The IBC chair, or his/her designee, assigns at least two members to serve as technical reviewers. The technical reviewers present their findings to other member of the committee at a properly convened IBC meeting for discussion.
- No member may participate in the IBC review or approval of a protocol in which the member has a conflicting interest (e.g. is personally involved in the project) except to provide information requested by the IBC; nor may a member who has a conflicting

interest contribute to the constitution of a quorum. At the beginning of each meeting the Chair of the IBC reminds investigators to declare any conflicting interest not previously disclosed.

IBC Actions Following Full Committee Review

Following review of the protocol, a motion is made and vote taken to either:

- 1) Approve as submitted
- 2) Approve, with minor modifications
 - a. Protocol goes to Chair for approval
- 3) Send for revisions and re-review
 - a. Protocol goes back to original 2 DMR for approval – can call for FCR if needed
- 4) Denial

If the motion is to require modifications (to secure approval), the motion must include how those modifications will be reviewed: 1) Designated Member Reviewers assigned or 2) FCR. When the motion is to review the modifications by DMR, the vote must be unanimous. All members of the IBC will be provided with an electronic copy of the revised protocol and may request FCR of the revised protocol at that time. Providing no one requests FCR, the assigned designated reviewers are authorized to approve or require further modification to secure approval and their decision must be unanimous.

Notification Following Review

The IBC Office will notify investigators in writing of its decision to approve or withhold approval of those activities related to biosafety, or of modifications required to secure IBC approval. The IBC procedures to notify investigators and the Institution of its decisions regarding the protocol review are as follows:

- The IBC Chair or his/her designee shall notify the investigator in writing of the IBC's decision to approve the protocol, require modification in (to secure approval), or withhold approval (disapproval). In order to secure approval the investigator must revise the IBC application and/or respond to other conditions set by the IBC.
- Investigators have 60 days after receipt of the written request to address the required modifications. After 60 days the protocol or change request will be withdrawn from the review process.

2.2.4 Approval Period of the Project

All protocols approved by the IBC will be approved for a five (5) year period. At the end of that period, a new IBC application must be submitted to the committee for reconsideration.

2.2.5 PI Initiation of the Project

Work done at BSL 2 and above, as well as projects involving non-exempt recombinant or synthetic nucleic acid must not proceed until the PI obtains formal written approval from the IBC and the lab/facility has been inspected by the Biological Safety Officer (BSO). In addition, work must not proceed until all other required notification is completed (e.g., notification to NIH/OBA when required), and approvals obtained (e.g., approval by the Institutional Animal Care and Use Committee (IACUC), Institutional Review Board (IRB), Radiation Safety Committee (RSC), APHIS permits, or other regulatory authorities, etc.).

2.2.6 Protocol Maintenance

On an annual basis, the PI is responsible for submitting an update (exempt protocols) or progress (rDNA protocols) report to the IBC Office, a status update of his/her project by confirming its continuation or completion. On an on-going basis, PIs are required to notify the IBC Office of all amendments to the approved protocol by submitting a change in protocol form. Substantial protocol amendments (e.g., changes in host vector systems, factors affecting the final risk assessment, etc.) are subject to review and approval by the IBC prior to initiation of the change. All correspondence related to an approved protocol must reference the protocol number assigned by the IBC Office.

2.2.7 Spills involving Recombinant or Synthetic Nucleic Acids, Infectious Agent or Human Blood, Bodily Fluid or Tissue

Spills involving any of these materials should be handled according to the NDSU [Biosafety Manual \(pg. 48\)](#)

2.2.8 Incident/Adverse Event Reporting

All NDSU incidents/accidents must be reported to the NDSU [UP&SO](#) immediately or within 24 hours by completing and submitting the NDSU [Incident Report Form](#).

If the event/incident involves recombinant or synthetic nucleic acids it must also be reported to the NDSU IBC Office within **24 hours** to meet the institutional requirements prescribed by the *NIH Guidelines*. The event must be reported by submitting the IBC [Adverse Event Reporting Form](#) available on the website.

The report is forwarded to the IBC for designated review of the incident and any corrective actions already taken or proposed by the PI.

2.3 Packaging and Shipping Dangerous Goods

Transport of human and animal infectious agents, diagnostic specimens, recombinant or synthetic nucleic acid molecules contained in an organism or in a viral genome shall be shipped under applicable regulations of the U.S. Postal Service (39 CFR Part 3); the U.S. Department of Agriculture (9 CFR, Subchapters D and E; 7 CFR Part 340); and/or the U.S. Department of Transportation (49 CFR Parts 100-185). Various regulatory requirements may pertain to the importation, exportation, or domestic transfer of a wide variety of potential biological agents.

Shipments of transgenic organisms are regulated by the USDA-APHIS office. Regulations and permitting requirements can be located on the following website: www.aphis.usda.gov/biotechnology/index.shtml

Shipments containing dry ice may be subject to additional regulations.

For information on shipping biological agents contact the Centers for Disease Control and Prevention at <http://www.cdc.gov/od/eaipp/shipping/>.

Notify and consult with the [UP&SO](#) if you suspect that any of these regulations may apply to your work activities.

2.4 Biological Waste

Appropriate waste handling is discussed in the [NIH Guidelines](#) and the [BMBL](#). General guidance for treatment of waste follows.

Contaminated animals (whole or parts), contaminated bedding, contaminated shipping containers, contaminated feeds or similar materials must be rendered non-hazardous. Pathological waste can also be picked up by an approved vendor and properly disposed. Call the [UP&SO](#) for information on this service.

2.4.1 Infectious Agents

Materials involving infectious agents must be rendered non-hazardous before disposal. Refer to the [UP&SO SOP – Biosafety Manual for more information](#).

2.4.2 Human blood, bodily fluid, and tissue waste

Waste of human origin must be rendered non-hazardous before disposal. Options for disposal can be arranged through the [UP&SO](#). . Refer to the [UP&SO SOP – Blood-borne Pathogen Exposure Control Plan](#) for more information.

2.4.3 Plant Waste

Plant waste generated in BL2-P and BL3-P projects must be made non-viable before disposal.

2.4.4 Recombinant and Synthetic Nucleic Acids

This includes waste products from laboratory research procedures involving recombinant and synthetic nucleic acids in plasmids, viral vectors, organisms used to

propagate recombinant and synthetic nucleic acids, cell cultures, as well as naked DNA from polymerase chain reaction (PCR) and sequencing reactions. It also includes tissue and cells harvested from animals containing recombinant and synthetic nucleic acids (e.g. transgenic animals). All of this waste must be rendered non-hazardous before disposal. Options for disposing can be arranged through the UP&SO.

2.5 Training

Supervisors must provide biosafety training to employees prior to them conducting or participating in any biosafety work. Additional relevant topics will likely include laboratory safety, biosafety, blood-borne pathogens, shipping and receiving of hazardous substances.

NDSU IBC training requirements can be found on the NDSU IBC website under the Training tab at http://www.ndsu.edu/research/integrity_compliance/ibc/training

Training is available on the Collaborative Institutional Training Initiative www.citiprogram.org

2.6 Facility Issues

2.6.1 Biological Safety Cabinets and Laboratory Ventilation

Biosafety cabinets must be certified annually or when moved. Certification, maintenance and repair of cabinets and associated ventilation in all facilities are provided by an outside vendor and arranged by departments or research units (USDA). PIs and laboratory personnel are prohibited from changing HEPA filters and from performing maintenance on the cabinets.

2.6.2 Insect and Rodent Control

Insect and rodent control is managed through the NDSU Facilities Management (FM) department.

For USDA facilities, insect, weed and fungus control can be requested by submitting an application-request form from the AES Greenhouse Complex.

<http://www.ag.ndsu.edu/greenhouse/pesticide-application-request-form>

2.6.3 Autoclaves

Autoclave standard operating procedures as well as autoclave performance verification information is available on the UP&SO website.

https://www.ndsu.edu/police_safety/environmental_health_and_safety/biological_safety/

3 Roles and Responsibilities

3.1 Senior Administrative Oversight

The NDSU Vice President for Research and Creative Activity (VPR) will appoint IBC members based on recommendations from Deans, Chairs, faculty and staff.

The IBC Office is responsible for:

- Filing the annual IBC membership roster with the NIH/Office of Biotechnology (OBA)
- Communicating with the IBC Chair, VPR, and the NIH/OBA, if necessary, regarding significant problems, violations of *NIH Guidelines*, or any significant research-related accidents and illnesses to NIH/OBA within 30 days
- Receiving recombinant or synthetic nucleic acid project protocols and notifying the IBC Chair of proposals that require institutional approval
- Assigning a recording secretary for IBC meetings and maintaining associated minutes
- Maintaining files, which are open to the public, of protocols and updates, registration documents, and minutes of meeting, and the IBC membership list.

3.2 Department Administrator

Department Heads/Chairs and/or Deans/Directors and/or Unit Research Leaders (USDA) are responsible for:

- Reviewing, and if in agreement, approving project protocols involving research activities listed in section 2.1 prior to the PI's submission to the IBC
- Ensuring that adequate facilities are available and maintained to properly support the proposed protocol

- Ensuring that biosafety requirements and safety policies and procedures are enforced at the departmental level.

3.3 Institutional Biosafety Committee

3.3.1 Membership

As mandated by the *NIH Guidelines*, the IBC must be comprised of no fewer than five (5) members so selected that they collectively have experience and expertise in recombinant or synthetic nucleic acids technology and the capability to assess the safety of recombinant or synthetic nucleic acids research and to identify any potential risk to public health or the environment.

- At least two (2) members of the IBC are not affiliated with NDSU (apart from their membership on the IBC) and who represent the interest of the surrounding community with respect to health and protection of the environment.
- At least one (1) member has expertise in plant, plant pathogen, or pest containment principles.
- At least one (1) member has expertise in animal containment principles.

When the institution conducts recombinant or synthetic nucleic acids research at BL3, BL4 or larger scale (greater than 10 liters), a Biological Safety Officer (BSO) is mandatory and shall be a member of the IBC.

When the institution participates in or sponsors recombinant or synthetic nucleic acids research involving human research participants, the institution must ensure the IBC has adequate expertise and training (using ad hoc consultants as deemed necessary).

According to the *NIH Guidelines*, in order to ensure the competence necessary to review and approve recombinant or synthetic nucleic acid activities it is recommended the IBC:

- Include persons with expertise in recombinant or synthetic nucleic acids technology, biological safety, and physical containment
- Include or have available as consultants person knowledgeable in institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes and the environment
- Include at least one member representing the laboratory technical staff.
- May include at least one graduate student

The VPR appoints committee members to a three (3) year term with the possibility of serving longer. The Chair is also appointed by the VPR. The members listed above are vested with voting rights. However, they must abstain from voting if they are engaged or have a vested interest in a project proposal before the committee for consideration.

IBC members are expected to:

- maintain a working knowledge of issues pertaining to the IBC by completing training on the CITI website www.citiprogram.org “Training for IBC members”
- when qualified, perform timely reviews of protocols
- disclose any conflict of interest with respect to review of research protocols
- attend meetings or notify IBC administrator of known absences
- actively participate in meeting discussion and deliberation

A quorum consists of at least 50% of the total membership of the committee and a vote of approval requires at least a simple majority. The Chair or designee must be present.

3.3.2 Responsibilities

The IBC is responsible for:

- Reviewing protocols involving activities listed in section 2.1 conducted at or sponsored by NDSU including:
 - the risk assessment performed by the PI and associated level of containment, facilities, and work practices;
 - assessing the adequacy of the training and experience of the PI to conduct the type of work proposed; and
 - evaluating the need for medical surveillance and/or preventative immunizations
- Notifying the IBC Office and the PI of the results of the IBC review and basis for approval or denial of the proposed project
- Reviewing annual updates of approved projects that are to continue
- Setting containment levels for certain experiments as described in the *NIH Guidelines*, specifically:
 - Section [III-D-2-a](#), *Experiments in which DNA from RG 2-3 or Restricted Agents are Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems*;
 - Section [III-D-4-b](#), *Experiments Involving Whole Animals*, and
 - Section [III-D-5](#), *Experiments Involving Whole Plants*

- Communicating with the NDSU VPR regarding accidents, illness, or other significant matters and assure reporting to NIH, if required, is completed
- Reporting to the PI, department administrator, VPR, as appropriate, if proper safety procedures are not being followed, or if appropriate safety equipment and facilities are not available to support work in section 2.1
- Communicating with the IACUC, the IRB, the RSC, and the Laboratory and Chemical Safety Committee regarding biosafety requirements/stipulations for BSL 2 and 3 protocols involving use of animals, humans, radioactive isotopes or toxic agents
- Reviewing risk assessment as applicable
- Adopting emergency plans and spill procedures.

3.4 Principal Investigator (PI)

PIs are responsible for:

- Adhering fully to applicable rules and regulations, standard practices, including but not limited to the *NIH Guidelines*, and the *BMBL*
- Developing, implementing, and adhering to specific established protocols
- Obtaining the required written approval from the department chair/head or unit research leader (USDA) prior to submitting protocol proposals to IBC
- As requested by the IBC, clarifying or modifying specific content matter of proposed protocols
- Developing a laboratory specific biosafety plan where existing plans do not address all the safety aspects of the project
- Adhering to and having adequate training/experience in all aspects of the approved protocol including observance of good microbial techniques, emergency plans, training plans, and related safety practices
- Obtaining approval from the IBC and providing annual updates to the IBC
- If appropriate, developing and implementing necessary medical surveillance and immunization programs for laboratory workers
- Making available to all laboratory personnel a copy of the written, approved protocol
- Training laboratory workers in good microbial techniques as well as practices, procedures, and techniques to avoid injury for at-risk tasks, including maintenance of written documentation of such training. Relevant topics could

include annual baseline safety, laboratory safety, biosafety, blood-borne pathogen, shipping and receiving of hazardous substances. Biosafety training must be completed on-line through the links on the IBC web site.

- Routinely supervising laboratory workers' performance to assure a safe workplace and correct work errors and conditions that are a risk to the worker or the environment
- Immediately reporting significant problems, violations of the *NIH Guidelines*, or injuries and illnesses attributable to occurrences in the laboratory to the department head/chair and the IBC Chair
- Complying with applicable shipping requirements
- Ensuring facilities and equipment are maintained to support the required BSL containment
- Enforcing laboratory access limitations to maintain adequate security
- Assessing project specific risks and if necessary preparing formal risk assessment
- Additional information regarding formal risk assessments may be found in the *NIH Guidelines*, [Section II](#) - *Safety Considerations*.

3.5 Laboratory Workers

Laboratory workers are responsible for:

- Being familiar with all protocols and agents used in the laboratory regardless of whether he/she directly works with them
- Knowing all emergency procedures established by the PI
- Reporting all occupational accidents, illnesses, and injuries
- Following all laboratory practices established by the PI
- Completing all required training.

3.6 Biological Safety Officer (BSO)

The BSO is responsible for:

- Periodic inspections to ensure laboratory standards are followed.
- Reporting to the IBC and the institution any significant problems, violations of the *NIH Guidelines*, and any significant research-related accidents or illnesses of which the BSO becomes aware unless the BSO determines a report has already been filed by the PI

- Developing emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving recombinant or synthetic nucleic acid molecule research
- Providing advice on laboratory security
- Providing technical advice to PIs and the IBC on research safety procedures.

4 Noncompliance and Corrective Actions

Projects that are noncompliant with requirements of the IBC may endanger human or animal health and/or the environment. Noncompliance may involve failure to comply with IBC requirements for:

- training
- protocol review and approval
- adherence to applicable biosafety standards (BSL1, BSL 2, or BSL 3)
- annual protocol updates and changes
- reporting exposures, accidents/injuries and accidental releases; or
- other requirements of the IBC.

If there is noncompliance suspected, a subcommittee of the IBC will request a meeting with the PI in question, to gather more information.

The IBC will require suitable corrective actions to prevent recurrence and ensure safety of human and animal health and/or the environment. Corrective actions may include, but are not limited to:

- additional training
- revision of risk assessment or biosafety level
- changes in procedures, equipment or facilities
- unannounced laboratory inspections
- restriction or suspension of IBC approval for a project,
- restriction or suspension of an investigator's role in a project, or any other action necessary to ensure safety.

A letter, outlining the corrective actions will be sent to the PI, along with their department chair/head after the subcommittee meets and determines what those actions should be. The IBC will also receive a copy of this letter. There will be a time limit on when the actions need to be completed as determined by the subcommittee. Some non-compliance will need to be reported to NIH.

5 Policy on Public Comments

- Section IV-B-2-a-(7) of the *NIH Guidelines* states that if the public comments on IBC actions, the institution will forward both the comments and the IBC response to NIH. This shall be handled by the Research & Integrity Compliance office.

6 Appeals Process

- Investigators shall have the right to appeal a decision of the IBC within two weeks of receipt of disapproval letter
- The appeal will be initiated by submitting a letter to the IBC Chair
- The Chair will determine if the appeal warrants another board discussion of the protocol with the PI present to present their justifications for approval

7 Annual report to NIH OBA

An annual report is submitted to NIH OBA detailing the IBC members as well as MOUs currently in place. The report is submitted by the IBC office.